



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,670	12/14/2001	Shmuel Sternberg	(DI-5763) 112713-136	2942

29200 7590 06/15/2004

BAXTER HEALTHCARE CORPORATION  
RENAL DIVISION  
1 BAXTER PARKWAY  
DF3-3E  
DEERFIELD, IL 60015

EXAMINER
----------

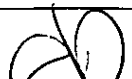
SIEFKE, SAMUEL P

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/024,670	Applicant(s) STERNBERG ET AL.	
	Examiner Samuel P Siefke	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on arguments 4/5/04.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed 4/5/04 have been fully considered but they are not persuasive. Applicant argues, "As fully supported in the specification, the ammonia sensing membranes of the present invention can be adapted for use, such as during dialysis therapy." The preamble of the claim reads "A method of providing dialysis therapy." The rejection is used because the claimed method provides using a ammonia sensor test strip for detecting ammonia in a dialysate solution. This is not aiding in **providing** dialysis therapy but only **detecting** ammonia in a dialysate solution. The Office suggests substituting the current preamble with "A method of detecting ammonia in a dialysate solution comprising the steps of" or something to that matter.

The Applicant argues, "nowhere does EP '045 reference disclose or arguably suggest an ammonia sensor membrane that includes a pH sensitive dye embedded within the porous structure of a membrane layer." The Office would like to point out that when one coats a porous hydrophobic membrane, the porous surface will accept the coating into the pores of the membrane. Therefore, the pH sensitive dye would be embedded within the porous structure.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **34-38** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 34-38 are directed to a method of providing dialysis therapy, but the claims only recite a method of detection and control.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1,3-8,10,11,15,17,20-23** are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1037045.

EP '045 discloses a quick acting toxic ammonia test for aqueous samples that comprises a porous (microporous; 1.2 microns, page 3, line 9-11) hydrophobic membrane layer including a polymeric compound containing fluorine (polyvinylidene fluoride; page 3, line 4) and a pH sensitive dye (bromophenol blue; page 3, lines 22) embedded within the porous structure of the hydrophobic membrane layer. The membrane layer is capable of calorimetrically sensing the gas (page 2, lines 20-21).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1743

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **25-38** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 1037045.

EP '045 discloses a quick acting toxic ammonia test for aqueous samples

EP '045 does not teach specifically of a pH sensitive dye embedded in the porous structure.

It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify EP '045 to embed the pH sensitive dye into the porous structure so the dye will not inadvertently be removed from the porous structure while monitoring the analyte. It would have been obvious to embed in all the pores in order to ensure complete reaction with the analyte. Regarding claim 25, providing an aqueous solvent solution and immersing the hydrophobic membrane in the aqueous solvent such that the pH sensitive dye is embedded within the microporous structure of the hydrophobic membrane. It would have been obvious to one having an ordinary skill

Art Unit: 1743

in the art to recognize that when a membrane is immersed in a solvent that both sides would be coated with the solvent containing the pH sensitive dye.

Claims **2, 9, 12-14, 16, 18, 19, 26-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1037045 in view of Ash (USPN 4,661,246).

EP '045 discloses a quick acting toxic ammonia test for aqueous sample as described above.

EP '045 does not teach the aqueous sample is a dialysate solution.

Ash teaches a dialysis instrument with dialysate side pump for moving body fluids. Ash teaches that a ammonia test strip is used for measuring the ammonia in the dialysate liquid (col. 9, line 65-col. 10, line 53). It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify EP '045 for measuring dialysis solution in order to prevent leaching of potentially toxic chemicals (ammonia) to the dialysate via a gas permeable membrane.

Regarding the rate at which a reaction occurs on the test strip. This would have been obvious to produce a colorimetric reaction under 3 seconds in order for providing real-time analysis.

Claims **24** is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1037045 in view of Werner, T., et al., "Ammonia-sensitive Polymer Matrix Employing Immobilized indicator Ion Pairs," Analyst, Vol. 120, June 1 1995, pp. 1627- 1631.

EP '045 discloses a quick acting toxic ammonia test for aqueous sample as described above.

EP '045 does casting solution under acidic conditions to form the ammonia sensing membrane such that the pH sensitive dye is embedded within a microporous structure of the hydrophobic membrane.

Werner teaches using a casting technique to make a hydrophobic membrane (page 1628). It would have been obvious to one having an ordinary skill in the art to modify EP '045 to use a casting technique to make the hydrophobic membranes because by using a casting technique, one can make any size of a hydrophobic membrane because casting allows one to have control of the thickness and shape of the membrane.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1743

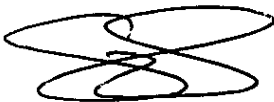
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



June 7, 2004



Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700